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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,196	12/04/2003	Orapin P. Rubino	1289-002US1	7287
47888 7590 12/23/2009 HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036				
EXAMINER				
HUANG, GIGI GEORGIANA				
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12/23/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/728,196

**Applicant(s)**

RUBINO ET AL.

**Examiner**

GIGI HUANG

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 15-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 30-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/06)  
Paper No(s)/Mail Date 4/2/2007, 10/12/2004
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I in the reply filed on June 29, 2009 is acknowledged. The traversal is on the grounds that the inventions have not been alleged or shown to be separate inventions. This is not found persuasive because the invention I was shown to be distinct from II and II due to their different classification, and Invention II and III were shown to be directed to different methods of manufacture with different machines and modes of granulation whereby different fields of search and queries would be utilized.

The requirement is still deemed proper and is therefore made FINAL.

As for the species election of the polymer, upon review the election is withdrawn.

Claims 15-29 are withdrawn from further consideration pursuant to 37 CFR

1.142(b), as being drawn to a nonelected invention.

It is noted that Applicant has renumbered claim 17 to be claim 18 again, creating two claim 18's. Claim 18(1st) is treated as claim 17 and claim 18 (2nd) is treated as claim 18. Correction is required.

Claims 1-14 and 30-34 are present for examination at this time

***Status of Application***

2. Applicant has elected Group I in response to restriction requirement and for the examination.

Due to restriction, based on election of Group I, claims 15-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

It is noted that Applicant has renumbered claim 17 to be claim 18 again, creating two claim 18's. Claim 18(1st) is treated as claim 17 and claim 18 (2nd) is treated as claim 18. Correction is required.

3. Claims 1-14 and 30-34 are present for examination at this time.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recited dependency to "any claim 8" which is indefinite as it is unclear if it is directed to claim 8 or a different claim or alternative claims not recited. The claim is also unclear as it recites the limitation of "said swellable polymer" in "any claim 8" wherein as addressed above, it is unclear which claim this is directed to as claim 8 itself does not have the limitation of a "swellable polymer" resulting in insufficient antecedent basis and indefiniteness as to claim dependency. As a result, the claim cannot be further treatment on its merits.
5. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recited dependency to "any claim 11" which is

indefinite as it is unclear if it is directed to claim 11 or a different claim or alternative claims not recited. The claim is also unclear as it recites the limitation of "said release rate controlling polymers" in "any claim 11" wherein as addressed above, it is unclear which claim this is directed to as claim 11 itself does not have the limitation of "rate controlling polymers" resulting in insufficient antecedent basis and indefiniteness as to claim dependency. As a result, the claim cannot be further treatment on its merits.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-10, 12 and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Samejima et al. (U.S. Pat. 4963365).

Samejima et al. teaches a controlled release dosage form with a core containing an medicament and excipients including binders and diluents (inner zone), an inner coating with ethylcellulose and a hydrophobic substance (e.g. talc, alkali earth metal stearates, calcium carbonate, colloidal silica), may have a middle coating layer with ethylcellulose or ethylcellulose and a water soluble substance, and an outer layer. The granules can also be placed in hard gelatin capsules which are exemplified. Example 1 has a core of diltiazem (69-.7%) with polyvinylpyrrolidone (7.0%) and lubricant/anti-aggregating-talc (5.8%), that is coated with an inner coating layer containing ethylcellulose and talc, middle layer (ethylcellulose, sucrose), outer layer, and surface

coating layer (all outer zone). Similar examples are present in Example 2 and 14-24, including granules in hard capsules and a layer with ethylcellulose (non-swellable polymer) and polyethylene glycol (Macrogol-swellable polymer) (Abstract, Col. 1 line 20-68, Col.2 line 30-60, Col. 3 line 9-21 line 40-Col. 4 line 5, Col. 4 line 32-44, Example 1-2, 14-24).

7. Claims 1-12 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Faour et al. (U.S. Pat. 6004582).

Faour et al. teaches a dosage form comprising an active in a core with excipients in the claimed ranges, with polymer and powdered coating comprising the polymers and the powders of the claims with actives (see full document, specifically Examples 1-8 and claims).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samejima et al. (U.S. Pat. 4963365) as applied to claim 1-5, 7-12 and 30-34 above, in view of Kjornaes et al. (U.S. Pat 4716041).

The teachings of Samejima are addressed above.

Samejima et al. does not expressly teach an example with the inclusion of microcrystalline cellulose in the outside the inner core.

Samejima does teach the use of talc, alkali earth metal stearates, calcium carbonate, colloidal silica in the general teaching and examples for the coatings (e.g. outer) with medicaments, binders, and a lubricant/anti-aggregating agent with the polymer and solvent (e.g. col. 3 line 40-64).

Kjornaes et al. teaches that anti-adhesives (lubricant/anti-aggregating) include metallic stearates such as magnesium stearate, calcium stearate, microcrystalline cellulose, colloidal silica, calcite (calcium carbonate), and talc are functional equivalents (Col. 6 line 11-18, Col. 7 line 50-58).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the talc with microcrystalline cellulose, as suggested by Kjornaes, and produce the instant invention. It is obvious to one of skill in the art to substitute one functionally equivalent lubricant/anti-aggregating agent for another based on pricing, availability, familiarity of use, or desired properties of the lubricant/anti-aggregating used to produce the final product.

One of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to have functionally equivalent choices to substitute the lubricant/anti-aggregating agent, when motivated by pricing, availability of the material, familiarity of use, or desired properties of the final product.

***Double Patenting***

9. Claims 1-14 and 30-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-17 and 31-34 of copending Application No. 11/596090. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application recites the same components, elements, and dosage forms (e.g. capsule) as the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Conclusion***

10. Claims 1-14 and 30-34 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH  
/Zohreh A Fay/  
Primary Examiner, Art Unit 1612